Document Control Specialist II

Job ID
REQ-10030821
Nov 22, 2024
USA

Summary

This position is responsible for documents, records, and training management activities as part of the Quality department. This position helps maintain the This position is responsible for documents, records, and training management activities as part of the Quality department. This position helps maintain the electronic data management system (EDMS) managing all controlled documents and records generated by Navigate BP, including, but not limited to, training records, audit records, corrective actions, memos, calibrations, and clinical study data records. This position will be responsible for supporting business needs related to the management and processing of electronic and paper documents and records throughout their complete lifecycle. The individual must work well in a rapid paced environment. The position requires the candidate to be flexible, organized, and have the ability to handle and prioritize many projects at a time. Works in a GMP/GCP/GLP/CLIA regulated environment and is responsible for following all applicable regulations.

This role is located on-site in Carlsbad, CA. Novartis is unable to offer relocation support for this role: please only apply if this location is accessible for you.

LI-#hybrid

About the Role

Key Responsibilities:

- Process the creation and revision of controlled documents in Master Control.
- Assists in MasterControl (EDMS) user account set-up, maintenance, and retirement.
- Assists in preparing reports regarding quality and training activities.
- Run reports and generate metrics as directed.
- Provide assistance and training with document, training, and record management processes.
- Create and maintain public organizers in MasterControl, as directed.
- Maintain job code, course, classroom, trainer, exam, and trainee data.
- Responsible for the physical and/or electronic archiving and retrieval of records including sending records to offsite vendor.
- Retrieve records in support of audits and other business needs and ensure traceability and integrity of records.
- Ensure job descriptions, CVs, license, and certifications are appropriately maintained.
- *Note: Other duties may be assigned.*

Essential Requirements:

- B.A. or B.S. preferred. In lieu of degree, will consider equivalent work experience that includes 2 years of direct document control/quality/GMP
- 2+ years of direct document control experience in a regulated industry preferred.
- Experience with document control activities and/or MasterControl is preferred;
- Effective knowledge of maintaining a document and data control system
- Effective organization and planning skills.
- Requires strong written, oral, interpersonal, and communication skills.
- Demonstrated ability to deal with frequent changes, delays, or unexpected events.
- Must be able to follow established policies and procedures, and comply with regulatory requirements.
- Demonstrated ability to perform detail-oriented work with a high degree of accuracy and completeness.
- Must be an expert user of Microsoft Word and Excel.

The pay range for this position at commencement of employment is expected to be between $33.32 and $49.95 per hour; however, base pay offered may vary depending on multiple individualized factors, including market location, job-related knowledge, skills, and experience. The total compensation package for this position may also include other elements, including a sign-on bonus, restricted stock units, and discretionary awards in addition to a full range of medical, financial, and/or other benefits (including 401(k) eligibility and various paid time off benefits, such as vacation, sick time, and parental leave), dependent on the position offered. Details of participation in these benefit plans will be provided if an employee receives an offer of employment. If hired, employee will be in an “at-will position” and the Company reserves the right to modify base salary (as well as any other discretionary payment or compensation program) at any time, including for reasons related to individual performance, Company or individual department/team performance, and market factors.

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EEO Statement:

The Novartis Group of Companies are Equal Opportunity Employers who are focused on building and advancing a culture of inclusion that values and celebrates individual differences, uniqueness, backgrounds and perspectives. We do not discriminate in recruitment, hiring, training, promotion or other employment practices for reasons of race, color, religion, sex, national origin, age, sexual orientation, gender identity or expression, marital or veteran status, disability, or any other legally protected status. We are committed to fostering a diverse and inclusive workplace that reflects the world around us and connects us to the patients, customers and communities we serve.

Accessibility & Reasonable Accommodations

The Novartis Group of Companies are committed to working with and providing reasonable accommodation to individuals with disabilities. If, because of a medical condition or disability, you need a reasonable accommodation for any part of the application process, or to perform the essential functions of a position,

please send an e-mail to us.reasonableaccommodations@novartis.com or call +1(877)395-2339 and let us know the nature of your request and your contact information. Please include the job requisition number in your message.

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Document Control Specialist II

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